RULES
OF
THE TENNESSEE MEDICAL LABORATORY BOARD
DIVISION OF HEALTH RELATED BOARDS

CHAPTER 1200-6-2
TRAINING PROGRAMS FOR MEDICAL LABORATORY PERSONNEL

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1200-6-2-.01 GENERAL REQUIREMENTS FOR ALL PROGRAMS.

(1) The Board shall approve the training programs which meet the requirements of one of the four (4) following general types:

(a) The Medical Laboratory Technologist Program

(b) The Medical Laboratory Technician - Associate Degree Program

(c) The Medical Laboratory Technologist Specialties Program

(d) The Public Health Clinic Laboratory Practitioner Program (only available to Local Health Departments operated by the State for training practitioners in each clinic laboratory.)

(2) All Programs for the training of Medical Laboratory Personnel to Apply for Approval.

(a) The owner and/or the director of a training program for medical laboratory personnel shall make application for approval to operate that program on forms provided by the Board at least six (6) months prior to anticipated first day of instruction.

(b) Each school shall be subject to on-site inspection by representatives of the Board and/or complete such paper surveys as requested.

(c) A scheduled on-site inspection to validate the initial application shall be conducted by representatives of the Board.

(d) The Board shall be notified immediately of any changes made in the operation of the training program such as a change of ownership, location, accreditation status, directorship, and/or instructors. A new certificate of approval will be issued in the event of change in either ownership or directorship of the training program. A change in ownership shall also include an exchange of stock in an incorporated school.

(Rule 1200-6-2-.01, continued)

(3) Fees Amount

(a)	Initial Training Program Application Fee	$200.00
	Annual Registration (Renewal) Fee	$100.00
	State Regulatory Fee	$ 5.00
(b)	Initial application fee for a Public Health Clinic Laboratory Practitioner Program-	$100.00

(c) The Certificate of Approval shall be for one (1) year and shall expire on December 3lst of any given year.

(4) Minimum Standards for Facilities, Equipment, and Materials for all Training Programs for Medical Laboratory Personnel.

(a) The Training Program must insure that adequate space, light, and modem operable equipment is available in the teaching laboratory and medical laboratory(ies) clinical rotation sites. All equipment used in the training program shall be subject to inspection and approval by the Board.

(b) Each training program for medical laboratory personnel shall have adequate classroom, laboratory, office, storage, and sanitary facilities which shall be subject to inspection and approval by the Board.

(c) A designated student laboratory area shall be available for teaching basic techniques, instrumentation and problem solving for procedures not available in the clinical facility(ies).

(d) Each training program facility for medical laboratory personnel must provide written documentation of compliance with local and state fire codes to the Board upon request.

(e) Written fire and safety procedures shall be made available to each student. Pertinent fire safety procedures shall be displayed in conspicuous places in the training program facility.

(f) A library containing up-to-date texts, references, and scientific periodicals pertinent to laboratory medicine as well as the latest editions of books and journals on laboratory technology shall be accessible to the Students. Texts required to be purchased by students must not be a substitute library [Older reference texts of value may be retained. Up-to-date is defined as published within the last five (5) years].

(g) Demonstration materials and multimedia instructional material shall be available as Rather provided under other sections of these regulations.

(h) An outline of the instruction provided, including a structured clinical laboratory practicum, shall be filed with the Board. When major revisions/changes are made in the curriculum, a new outline shall be submitted to the Board.

(i) A description of evaluation procedures for both student and program shall be submitted to the Board upon making application for approval of the Training Program. These evaluations shall be maintained for future inspection by the Board or its designee. Provision must be included for periodic review of the effectiveness of the program by members of the faculty and/or other appropriate groups. Student evaluation procedures must include mechanisms to measure cognitive knowledge, psychomotor and affective behavior.

(j) Student recruitment, admission and matriculation must be nondiscriminatory with respect to color, creed, race, sex, age, handicap(s), and national origin.

(k) Satisfactory records must be kept and shall be available for inspection by the Board. These shall include but not be limited to:

1. A list of instructors, by category, in the training program and clinical laboratory facilities. This list shall be submitted with initial application and thereafter upon request;

2. Current examinations given to students;

3. Scores on licensure examinations;

4. Records of students, including:

(i) A complete application form;

(ii) Transcript of academic credit;

(iii) Written evidence the student can reasonably be expected to perform the medical laboratory work for which he/she is trained which must include a recent complete physical examination performed by a licensed medical practitioner prior to beginning clinical rotation;

(iv) Record of attendance, including excused and unexcused absences; and

(v) Evaluation by instructors based on appropriate written, practical, and oral examinations covering all types of structured learning experiences (clinical and classroom) related to the medical laboratory.

(l) The program shall be approved for a specific number of students which shall not be exceeded without prior approval by the Board.

(m) There shall be an affiliation agreement between the educational institution and the licensed laboratory agreeing to serve as the clinical rotation site. The agreement shall state the responsibilities of each party regarding the clinical training of the students enrolled in that program and instructions from each clinical facility for exchange of information and views. The affiliation agreement shall be submitted to the Board upon initial application for training program approval and thereafter prior to any change in clinical rotation sites.

(5) Clinical Facilities and Approved Laboratory Experience - Practicum (bench training).

(a) Programs for the training of medical laboratory personnel shall be approved only when they are affiliated with a hospital(s) or a medical laboratory(ies) for clinical experience (practicum).

The training program may be affiliated with in-state licensed laboratories or out-of-state CLIA certified laboratories. The clinical facility(ies) shall be approved in advance by the Board.

(b) Clinical facilities with a balanced distribution of clinical laboratory material shall meet the following minimum standards in order to train students:

1. Medical laboratory technologist (general and specialties) and associate degree technician: The medical laboratory(ies) must be associated with, or connected to, a general medical and surgical hospital with a minimum of 7,500 annual admissions and must perform a minimum of 200,000 laboratory procedures a year to qualify to train a student body of ten (10) students.

Larger student bodies will require proportionately larger number of annual admissions and laboratory procedures.The total number of admissions and laboratory procedures need not all be in the same facility/laboratory, but may be the sum of the admissions and laboratory procedures in two or more institutions.

2. The medical laboratory training program Director and/or Education Coordinator must assume responsibility for arranging the approved clinical laboratory experience (practicum) for the student with an affiliated facility(ies). It shall be a violation of these regulations to grant a diploma to any student who has not completed an approved clinical laboratory experience (practicum).

3. Trainee applications shall be submitted for each student prior to the beginning of the approved clinical laboratory experience (practicum). The Board will then issue a trainee permit to the applicant provided they are in an approved facility. No student shall perform laboratory tests without a valid trainee permit.

4. If there is a change in the clinical rotation site at which the student will gain the clinical laboratory experience (practicum), the Board shall be notified before the student is placed in the new facility.

(6) The Use of Students as Substitutes for Licensed Medical Laboratory Personnel. No training program substituting students (trainees) for licensed medical laboratory personnel shall be approved. Using students (trainees) to perform laboratory procedures without adequate supervision shall result in withdrawal of training program approval and shall subject the training program to disciplinary action as provided for in the Tennessee Medical Laboratory Act.

(7) Copies of the Law and Regulations to be given to the students. A copy of the Tennessee Medical Laboratory Act and the regulations promulgated thereunder shall be given to each student. The Board shall provide the training program with copies of these documents upon request.

(8) Training Programs for Medical Laboratory Technologists and Technicians to be separate. Training Programs for the training of medical technologists and technicians shall be separate and distinct, and students in each class should have separate instruction in the classroom and in the clinical facility(ies).

(9) Penalty for making misrepresentations to prospective students. Any owner, director, personnel, or agent of a school for the training of medical laboratory personnel who misrepresents facts concerning the facility(ies), student training, or any other facet of the school to prospective students shall be subject to withdrawal of approval of said school. This shall include but not be limited to:

(a) Announcements and advertising must accurately reflect the program offered.

(b) Student recruitment and academic policies shall be non-discriminatory with respect to race, color, creed, sex, age, handicap(s), and national origin.

(c) Academic credit and costs to the student shall be accurately stated, published and made known to all applicants.

(d) Policies and procedures for student withdrawal and refunds of tuition and fees shall be published and made known to all applicants upon admission-

(e) If more than one level of medical laboratory educational program is offered at one institution, e.g., Medical Technology and Medical Laboratory Technician, the institution must demonstrate that each program is being conducted to assure appropriate instruction for the students at the different educational levels.

(Rule 1200-6-2-.01, continued)

(f) The program must culminate in either a baccalaureate or an associate degree. The granting of the degree must not be contingent upon the student's passing any type of external certification or licensure examination.

(g) In the event that the program is discontinued or restructured, the program should provide a plan for the protection of its students accepted or enrolled in the program.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Amendment filed June 30, 1987; effective August 14, 1987. Amendment filed July 13, 1990; effective August 27, 1990. Amendment filed February 21, 1991; effective April 7,1991. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-6-2-.02 FACULTY REQUIREMENTS FOR MEDICAL LABORATORY TRAINING PROGRAMS.

(1) Medical Director/Advisor

(a) The following programs shall have a medical director/advisor:

1. The Medical Laboratory Technologist Program

2. The Medical Laboratory Technician Program - Associate Degree

3. The Medical Laboratory Technologist Specialty Training Program

(b) Qualifications:

1. The medical director/advisor shall be a physician who is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or who possesses qualificationswhich are equivalent to those required for such certification (Board eligible).

2. The medical director/advisor shall be licensed to practice medicine in Tennessee.

(c) The director of the Program for Training Medical Laboratory Specialties shall meet one of the minimum qualifications of Medical Laboratory Director, as set forth in Rule 1200-6-l-.20 of the regulations governing the Tennessee Medical Laboratory Act. The program he or she directs must be related to his/her training.

(2) Program Director/Education Coordinator. Each Program shall have either a Program Director or Education Coordinator. In the case of a program for the training of medical laboratory specialties, the director may serve as program director.

(a) Program Director.

1. A program director is defined as the responsible licensed technologist based in a university, junior college, or hospital program who meets the following criteria:

(i) Has a faculty appointment either in the approved academic institution or an affiliated institution.

(ii) Has documented evidence of continuing education in technical and educational methodologies to provide adequate and appropriate training in the areas of curriculum design and teaching techniques for medical laboratory personnel.

(Rule 1200-6-2-.02, continued)

(iii) Has the major responsibility for directing the educational program.

(iv) Is at least a licensed technologist with a baccalaureate degree. A master's degree or higher is recommended.

(v) Has at least three (3) years experience in a clinical laboratory, including teaching experience acceptable to the Board in a clinical laboratory under the supervision of a licensed physician who meets the qualifications of Medical Laboratory Director as set forth in Rule 1200-6-1-.20 promulgated pursuant to Tennessee Medical Laboratory Act.

(vi) Is free from service responsibilities to accomplish his/her teaching, educational, and administrative responsibilities with the medical or specialty director of the program.

2. Duties of the program director. In consultation with the medical of specialty director, education coordinator, and faculty, the program director is responsible for overall direction of the program.

(b) Education Coordinator.

1. Education Coordinator is defined as the responsible licensed technologist serving as liaison between the program administration and other institutions involved in the clinical experience.

2. The education coordinator shall be at least a licensed technologist and have a baccalaureate degree plus three (3) years of experience in a clinical laboratory

3. The education coordinator must be sufficiently free from service responsibilities to accomplish teaching, educational, and administrative responsibilities.

4. The education coordinator will share responsibilities with the program director for the organization and operation of the program, including classroom and laboratory instruction.

(c) Instructor (Classroom and Clinical) Credentials:

1. All instructors of medical laboratory subjects shall be licensed medical laboratory personnel or have met the education requirements of not less than those required in these Rules for a medical laboratory technologist. Credentials for qualification must be submitted on forms supplied by the Board. The Board may query instructors during the on-site inspection. Such information gained from an instructor may be used in the determination, approval, or denial of the training program's application if there is a doubt about his knowledge of a subject. The Board will require all unlicensed instructors to take and pass the State Licensure Examination at the technologist level in the specialty(ies) taught.

2. Instructor Student Ratio: In the clinical laboratory training facility(ies), the number of licensed qualified personnel must be adequate to meet both service and teaching responsibilities. It shall be the responsibility of the medical and program directors to insure that the number of instructors is adequate to provide appropriate instruction in all areas of the program. When students are present in the laboratory, a licensed technologist shall be present and shall be responsible for supervising their education.

(Rule 1200-6-2-.02, continued)

(i) For classroom didactic instruction, there must be a student-faculty ratio of no more than 30: 1.

(ii) Student laboratories must have a student-instructor ratio of no more than 10: 1.

(iii) Clinical laboratory experience (internship) must not exceed a ratio of two students to one (2: 1) qualified instructor in any rotation area.

(3) The medical or specialty director/advisor shall share with the program director and/or education coordinator the responsibility for the organization and operation of the program including classroom and laboratory instruction. The medical or specialty director should be available for orientation and available as a student advisor for clinical problems as needed. The medical or specialty director shall give a minimum of one (1) lecture to each class of students.

(4) The division of responsibility and authority between the medical or specialty director and program director or education coordinator within each institution shall be clearly established in writing.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-10, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-6-2-.03 THE MEDICAL LABORATORY TECHNICIAN ASSOCIATE DEGREE PROGRAM MINIMUM REQUIREMENTS.

(1) Minimum Institutional Requirements:

(a) Programs for the Medical Laboratory Technician-Associate Degree Program shall be conducted by accredited junior or community colleges, technical institutes, or universities and colleges offering an associate degree.

(b) The Medical Laboratory Technician - Associate Degree Program must result in the granting of an associate degree.

(c) Where part of the instruction is provided by an educational institution and part is provided in a hospital or other laboratory facility(ies), approval shall be given to the educational institution's program- The parent educational institution may affiliate with several laboratories, and shall be responsible for coordinating instruction, maintaining standards, and evaluating student progress.

(2) Minimum Prerequisites for Admission of Students:

(a) Applicants for medical laboratory technician-associate degree programs must meet the admission requirements established by the sponsoring educational institution. Arrangements shall be available whereby student credits can be accepted from other medical laboratory programs; or,

(b) Students may be accepted with advanced standing by one of the institutions mentioned in subparagraph (1)(a) (above) on the basis of transfer credits or equivalent examinations but not on the basis of experience alone. Documentation of such arrangements shall also be a part of the student's record.

(3) Minimum Curriculum Requirements and Standards:

(Rule 1200-6-2-.03, continued)

(a) The medical laboratory technician-associate degree program is a total educational program; hence, the general educational and clinical laboratory segments shall be integrated to the greatest extent possible.

(b) Occupational competence in the medical laboratory shall be the prime objective of the total program and curriculum shall be planned to achieve this objective.

(c) The program shall be a structured educational curriculum comprised of general education, laboratory sciences (including clinical laboratory) and related subjects.

(d) The student's training must be limited to medical laboratory procedures and related subjects. No other subjects covering unrelated fields of study, such as x-ray, can be taught during this period of time.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-6-2-.04 THE MEDICAL LABORATORY TECHNOLOGIST SPECIALTY PROGRAM M1NIMUM REQUIREMENTS.

(1) Minimum Institutional Requirements:

(a) A specialty program may be conducted in one of the following ways:

1. An integrated program in an accredited college or university that will culminate in at least a baccalaureate degree in one of the medical laboratory specialties.

2. A one year program for students (trainees) who already possess a baccalaureate degree in a chemical, physical or biological science. The program shall consist of appropriate didactic classroom instruction. The remainder of the year shall be spent in gaining meaningful clinical laboratory experience in the applicable specialty.

(b) Specialty programs may be conducted by hospitals or other institutions approved in advance by the Board.

(c) The program shall consist of a minimum of six (6) months of clinical laboratory experience in an approved clinical facility.

(2) Minimum prerequisites for admission of students: The prerequisites for all specialty programs shall be those approved in advance by the Board.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-6-2-.05 MEDICAL LABORATORY TECHNOLOGIST TRAINING PROGRAM MINIMUM REQUIREMENTS.

(1) Minimum Curriculum Requirements:

(Rule 1200-6-2-.05, continued)

(a) The program must provide a structured curriculum that documents the clinical education with clearly written program goals and a course syllabus which includes both individual course objectives and competency levels to be achieved. The curriculum shall include all the major subject areas commonly offered in the modem clinical laboratory. Objectives which address the cognitive, psychomotor, and affective domains must be provided for didactic and clinical aspects of the program and must include clinical significance. These course objectives shall show progression to the level consistent with entry into the profession. The curriculum shall include:

1. Principles and methodologies for all major areas commonly practiced by a modem clinical laboratory,

2. Clinical significance of laboratory procedures in diagnosis and treatment;

3. Principles and practices of quality assurance;

4. Principles of laboratory management, supervision, safety, and problem solving;

5. Educational methodology; and

6. Computer application in the clinical laboratory sciences.

(b) Educational programs for medical laboratory technologists shall be conducted by accredited colleges and universities, hospitals, or other institutions that have been approved in advance by the Board.

(2) Minimum Prerequisites for Admission of Students:

(a) The educational prerequisites for admission to schools for medical laboratory technologists shall be three (3) years of academic study plus one (1) year of a training program (3+1) with graduation (or equivalent) from high school and successful completion of 90 semester hours (13 5 quarter hours) of academic credit in a college or university accredited by the Southern Association of Colleges and Secondary Schools or an equivalent thereto. The 90 semester hours (135 quarter hours) shall be acceptable as the first three (3) years of a baccalaureate program. During the three (3) years of collegiate education, the following courses shall be required:

1. Chemistry: A minimum of 16 semester hours (24 quarter hours) credit is required. Organic chemistry or biological chemistry must be included. Quantitative analysis and physical chemistry are recommended.

2. Biological Science: A minimum of 16 semester hours (24 quarter hours) credit is required. Microbiology (bacteriology) and immunology must be included in the curriculum. Genetics, anatomy, and physiology are recommended.

3. Mathematics: Three (3) semester hours (four and one half (4.5) quarter hours) credit in pre-science mathematics is required. Minimum requirements are met by course recognized as prerequisites for admissions to physics courses, except that the content of chemistry, biological sciences, and mathematics courses, shall be acceptable toward a major in those subjects of study. Survey courses do not qualify as fulfillment of chemistry, biological sciences, and mathematical prerequisites.

(b) The educational prerequisites for admission to a medical laboratory technologist integrated program (based in a college or university) shall be graduation from high school or equivalent and successful completion of a minimum of 60 semester hours (90 quarter hours) of academic credit in a college or university accredited by Southern Association of Colleges and Secondary Schools (or equivalent). The total program must include the courses mentioned in part (2)(a), subparts 1., 2., and 3. above.

(3) Additional Administrative Requirements:

(a) Unless a student is given equivalent credit by examination, the curriculum shall consist of a minimum of 12 months of structured educational experience.

(b) Clinical laboratory experience acceptable to the Board shall be included in the college or university-based programs.

(c) Reasonable vacation or sick leave may be granted at the discretion of the director. General rules regarding this should be in the programs brochure/student handbook.

(d) Students shall be oriented in medical ethics and institutional functions or regulations at the beginning of their clinical experience.

(e) The curriculum shall be comprised of all the major subjects commonly involved in the modem clinical laboratory. The curriculum must also include but not be limited to:

1. Principles of representative procedures and instruments: clinical significance of laboratory procedures in diagnosis and treatment including normal values; principles and practices of quality control and problem solving;

2. Principles of laboratory organization, management, and supervision;

3. Uses of laboratory data by physicians in patient management; and

4. Such other topics which may be of value in laboratory medicine.

(f) A complete outline of the curriculum must be submitted to the Board with the application form for approval to operate. It must include:

1. Expected capability of the graduates (what they should be able to do and at what level of competence);

2. Outline of learning experience, including:

(i) Lecture outlines;

(ii) Demonstrations; and

(iii) Laboratory rotational plan;

3. Description of procedures to be used in evaluation of knowledge, performance, professional attitude, and competence. Criteria for pass/fail decisions should be established and failing performance must be documented; and

4. A grievance process for student objections.

(Rule 1200-6-2-.05, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105 and 68-29-110.* ***Administrative History:*** *Original rule filed October 26,1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997*

1200-6-2-.06 CONTENTS OF APPLICATIONS FOR ADMISSION TO TRAINING PROGRAMS

(1) The applicant to each program for the training of medical laboratory personnel shall submit the following information:

(a) Personal history data:

1. Name, permanent address, local address, telephone number, parent's or guardian's name (address and telephone number if appropriate);

2. Date of birth, place of birth, citizenship status, and marital status;

3. Employment record;

4. Military service record (form DD214); and

5. Social Security Number;

(b) A transcript of college credits where indicated; and

(c) Evidence of good health which shall consist of a record of medical history and a complete physical examination certified by a physician as defined in the Tennessee Medical Laboratory Act. Included in the medical record shall be the results of a recent tuberculin test and also the results of a roentgenogram examination of the chest if the tuberculin test is found positive.

(2) All records of students shall be kept on file for a minimum of ten (10) years.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*

1200-6-2-.07 CURRICULUM REQUIREMENT FOR A PROGRAM FOR TRAINING OF PUBLIC HEALTH CLINIC LABORATORY PRACTITIONERS.

(1) A Public Health Clinic Laboratory Practitioner must complete Public Health Clinic Laboratory Practitioner Training Program consisting of a general laboratory practice core. The procedures will be standardized across the state to ensure continuity and conformity. Proof of training in the following areas will be maintained in the Practitioner's file on site:

(a) Laboratory Procedures;

(b) Quality Control;

(c) Instrumentation;

(d) Preventive Maintenance;

(e) Laboratory Safety;

(Rule 1200-6-2-.07, continued)

(f) Mathematics;

(g) Medical Terminology; and

(h) Phlebotomy

(2) After completion of the appropriate training, the Public Health Clinic Laboratory Practitioner must competently:

(a) Prepare and/or instruct a patient correctly for collection of laboratory specimens;

(b) Obtain specimens from patients, including specimens to be sent to referral laboratories, and process them according to acceptable procedures for the given test methodology;

(c) Record appropriate information that will correctly identify the patient and test performed, or referred, according to acceptable standards;

(d) Perform tests designated in Rule 1200-6-1-.25(4);

(e) Explain and perform quality control procedures appropriate for a Public Health Clinic Laboratory Practitioner. If quality control results are outside established limits, the Public Health Clinic Laboratory Practitioner must document that the appropriate corrective action has been taken before any test result is reported;

(f) Document quality control and instrument preventive maintenance according to acceptable standards;

(g) Demonstrate satisfactory performance on unknown sample(s);

(h) Follow safe laboratory practices to prevent infection and/or exposure to self and others; and

(i) Implement an appropriate inventory control system-

(3) All Training will be performed by qualified instructors under the direction of the Training Section of the Tennessee Department of Health, Laboratory Services, 630 Hart Lane, Nashville, TN 37247-0801.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-29-105, and 68-29-110.* ***Administrative History:*** *Original rule filed October 26, 1979; effective December 10, 1979. Repeal and new rule filed January 7, 1997; effective March 23, 1997.*